DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 6, 2015

Medline Industries, Inc.
Matt Clausen
Sr. Regulatory Affairs Specialist
One Medline Place
Mundlelein, IL 60060

Re: K143693
Trade/Device Name: Medline Sharps Containers
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MMK
Dated: November 2, 2015
Received: November 5, 2015

Dear Mr. Clausen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143693

Device Name
Medline Sharps Containers

Indications for Use *(Describe)*
Medline Sharps Containers are intended to provide a receptacle for used, contaminated medical sharps and act as an enclosure during transport to ultimate disposal.

Medline Model No.	Capacity	Lid Configuration	Dimensions of Lid Opening (aperture)	Weight of Finished Good (lbs)	Dimensions of Finished Good (L x W x H)	Color
MDS701201	1 GALLON	Sliding	5.5” x 2.25”	0.681	6.88”x 10.06”x 4.5”	Red
MDS701201F **	1 GALLON	Counter-Balanced	8.75” x 1.75”	0.752	6.88”x 10.06”x 6.25”	Red
MDS705201	1 GALLON	Sliding	5.5” x 2.25”	0.676	6.88”x 10.06”x 4.5”	Red
MDS705201F **	1 GALLON	Counter-Balanced	8.75” x 1.75”	0.747	6.88”x 10.06”x 6.25”	Red
MDS701202	2 GALLONS	Sliding	5.5” x 2.25”	1.014	6.88”x 10.06”x 9.5”	Red
MDS701202F **	2 GALLONS	Counter-Balanced	8.75” x 1.75”	1.085	6.88”x 10.06”x 11.25”	Red
MDS705202	2 GALLONS	Sliding	5.5” x 2.25”	1.002	6.88”x 10.06”x 9.5”	Red
MDS705202F **	2 GALLONS	Counter-Balanced	8.75” x 1.75”	1.073	6.88”x 10.06”x 11.25”	Red
MDS705208HN	8 GALLONS	Hinged	16.5” x 5.75”	2.491	12.5”x 18.25”x 11”	Red
MDS705208SL	8 GALLONS	Sliding	9” x 8.5”	2.884	12.5”x 18.25”x 11.5”	Red
MDS705208ST	8 GALLONS	Star	1.75” x 1.75”	2.551	12.5”x 18.25”x 12.38”	Red
MDS705210HN	10 GALLONS	Hinged	16.5” x 5.75”	2.813	12.5”x 18.25”x 14”	Red
MDS705210SL	10 GALLONS	Sliding	9” x 8.5”	3.206	12.5”x 18.25”x 14.5”	Red
MDS705210ST	10 GALLONS	Star	1.75” x 1.75”	2.873	12.5”x 18.25”x 15.38”	Red
MDS705212HN	12 GALLONS	Hinged	16.5” x 5.75”	3.311	12.5”x 18.25”x 17”	Red
MDS705212SL	12 GALLONS	Sliding	9” x 8.5”	3.704	12.5”x 18.25”x 17.5”	Red
MDS705212ST	12 GALLONS	Star	1.75” x 1.75”	3.371	12.5”x 18.25”x 18.38”	Red
MDS705218HN	18 GALLONS	Hinged	16.5” x 5.75”	4.269	12.5”x 18.25”x 28”	Red
MDS705218SL	18 GALLONS	Sliding	9” x 8.5”	4.662	12.5”x 18.25”x 28.5”	Red
MDS705218ST	18 GALLONS	Star	1.75” x 1.75”	4.329	12.5”x 18.25”x 29.38”	Red

* Intended for areas with no unsupervised patient access for the container models that do not have features to prevent hand and finger access to the sharps waste.

** Intended for use with mounting accessories.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and
Human Services Food and
Drug Administration
Office of Chief Information
Officer Paperwork
Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary (as required per 21 CFR 807.92)

Summary Preparation Date

November 6, 2015

Submitter / 510(k) Sponsor

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060

Contact Person

Matt Clausen
Sr. Regulatory Affairs specialist
Phone: 847-643-4785
Fax: 847-643-4482

Device Name / Classification

Device Name: Medline Sharps Containers
Proprietary Name: Medline Sharps Containers
Common Name: Sharps Container
Classification Name: Hypodermic single lumen needle (21 CRF 880.5570, product code – MMK, Class II)

Predicate Device

Medline Sharps Container, K132767

Comparison of Subject and Predicates

Characteristic	Proposed Device	Predicate Device	Comparison
510(k)	K143693	K132767	n/a
Product Code	MMK	M	Same
Regulation No.	21 CRF 880.5570	21 CRF 880.5570	Same
Class	II	II	Same
Indications For Use	Medline Sharps Containers are intended to provide a receptacle for used, contaminated medical sharps and act as an enclosure during transport to ultimate disposal.	Medline Sharps Containers are intended to provide a receptacle for used, contaminated medical sharps and act as an enclosure during transport to ultimate disposal.	Same

Size	1G / 2G / 8G / 10G / 12G / 18G	1Qt / 5Qt	Sizes are different
Dimensions (mm)	177 x 259 x 123 / 177 x 259 x 265 / 322 x 470 x 332 / 322 x 470 x 409 / 322 x 470 x 489 / 322 x 470 x 765	95 x 95 x 153 / 265 x 113 x 233	Different
Weight range (grams)	303 - 2388	107 - 360	Different
No. of Pieces	2-3	2-3	Same
Material	Poly-propylene	Poly-propylene	Same
Base Color	Red	Re	Same
Clarity	Opaque/translucent	Opaque/translucent	Same
Method of Manufacture	Injection Molded	Injection Molded	Same
Performance testing (puncture, impact, drop, stability, integrity)	Pass	Pass	Same
Technical characteristics	Refer to statement in Summary of Technological Characteristics section	Refer to statement in Summary of Technological Characteristics section	Same
Lid configurations / aperture dimensions	Refer to table below in Indication For Use section	Container capacities are different; dimensions are different	Different
Accessories	Mounting accessories (brackets) are available for use with 1g and 2g containers in locking and non-locking variations.	None	Different

Device Description

Medline Sharps Containers are two-piece conventional, disposable sharps containers. The base container and its lid are made of puncture resistant, leak proof polypropylene. These containers are offered in various volumes, sizes, and lid styles. Mounting accessories (brackets) are available for use with 1g and 2g containers in locking and non-locking variations. The device is intended to be used by qualified personnel in health care facilities and other facilities in which medical sharps may be used. The device is not in contact with or available to the patient in normal use.

Indications for Use

Medline Sharps Containers are intended to provide a receptacle for used, contaminated medical sharps and act as an enclosure during transport to ultimate disposal.

Medline Model No.	Capacity	Lid Configuration	Dimensions of Lid Opening (aperture)	Weight of Finished Good (lbs)	Dimensions of Finished Good (L x W x H)	Color
MDS701201	1 G	Sliding	5.5” x 2.25”	0.681	6.88”x 10.06”x 4.5”	Red
MDS701201F * / **	1 G	Counter-Balanced	8.75” x 1.75”	0.752	6.88”x 10.06”x 6.25”	Red
MDS705201	1 G	Sliding	5.5” x 2.25”	0.676	6.88”x 10.06”x 4.5”	Red
MDS705201F * / **	1 G	Counter-Balanced	8.75” x 1.75”	0.747	6.88”x 10.06”x 6.25”	Red
MDS701202	2 G	Sliding	5.5” x 2.25”	1.014	6.88”x 10.06”x 9.5”	Red
MDS701202F * / **	2 G	Counter-Balanced	8.75” x 1.75”	1.085	6.88”x 10.06”x 11.25”	Red
MDS705202	2 G	Sliding	5.5” x 2.25”	1.002	6.88”x 10.06”x 9.5”	Red
MDS705202F * / **	2 G	Counter-Balanced	8.75” x 1.75”	1.073	6.88”x 10.06”x 11.25”	Red
MDS705208HN	8 G	Hinged	16.5” x 5.75”	2.491	12.5”x 18.25”x 11”	Red
MDS705208SL	8 G	Sliding	9” x 8.5”	2.884	12.5”x 18.25”x 11.5”	Red
MDS705208ST	8 G	Star	1.75” x 1.75”	2.551	12.5”x 18.25”x 12.38”	Red
MDS705210HN	10 G	Hinged	16.5” x 5.75”	2.813	12.5”x 18.25”x 14”	Red
MDS705210SL	10 G	Sliding	9” x 8.5”	3.206	12.5”x 18.25”x 14.5”	Red
MDS705210ST	10 G	Star	1.75” x 1.75”	2.873	12.5”x 18.25”x 15.38”	Red
MDS705212HN	12 G	Hinged	16.5” x 5.75”	3.311	12.5”x 18.25”x 17”	Red
MDS705212SL	12 G	Sliding	9” x 8.5”	3.704	12.5”x 18.25”x 17.5”	Red
MDS705212ST	12 G	Star	1.75” x 1.75”	3.371	12.5”x 18.25”x 18.38”	Red
MDS705218HN	18 G	Hinged	16.5” x 5.75”	4.269	12.5”x 18.25”x 28”	Red
MDS705218SL	18 G	Sliding	9” x 8.5”	4.662	12.5”x 18.25”x 28.5”	Red
MDS705218ST	18 G	Star	1.75” x 1.75”	4.329	12.5”x 18.25”x 29.38”	Red

* Intended for areas with no unsupervised patient access for the container models that do not have features to prevent hand and finger access to the sharps waste.

** Intended for use with mounting accessories.

Summary of Technological Characteristics

The subject device and predicate device differ in container dimensions; sharps aperture features; use of mounting accessories and container capacities. The differences in design are intended to address specific site and user needs. Any risks resulting from design differences from the predicate device have been adequately mitigated with the performance testing, site-of-use labeling, and use with appropriate mounting accessories. The differences in technological characteristics do not impair the subject device models from their intended functions of disposal and storage of sharps waste.

Summary of Non-Clinical Testing

The safety and effectiveness of the Medline Sharps Containers are adequately supported by the substantial equivalence information, materials information, and Design Control activities referenced within this Premarket Notification.

Summary of Performance Testing

Test Objective	Testing Standards	Performance Results
Container Stability	BS EN ISO 23907	Meets ISO 23907 Requirements - Specimens were placed on a surface with an inclination of 15° in the most adverse position for toppling with no more than 0 failures per container.
Handle Strength	BS EN ISO 23907	Meets ISO 23907 Requirements - The sharps containers were filled to 50% of the fill line with de-ionized water and were then suspended by the handles for a period of at least 60 minutes; no failures were observed.
Puncture Resistance	ASTM F 2132	Meets ASTM F 2132 Requirements - Container was secured to the test apparatus using a specimen support plate with a 6mm diameter hole. The inside surface of the container was facing towards and perpendicular to the 21 gauge, 1 inch long needle. The needle was lowered vertically towards the test specimen at a rate of 100 mm/min, and was allowed to penetrate the test specimen; the puncture force was recorded. Per the acceptance criteria the average force was required to be greater3.4 lbf (15 N), and no single value from any region was allowed to be below 2.8 lbf.
Resistance to Damage (Drop/Impact Test)	BS EN ISO 23907	Meets ISO 23907 Requirements – Drop tested at height of 1m per test standard. Testing resulted in no evidence of leakage or damage resulting in a breach of the sharps containment area. As such, all Medline products were found to meet the acceptance criteria for resistance to damage from a vertical drop. Additional 1m drop testing was conducted using subject containers with a 40 lb. load or capacity load (23 lbs. for smaller

		sharps container), intended to simulate OSHA safe lifting limits. Five containers were used for each test orientation for each tested model. The test allowed only a single failure per test condition. The containers passed this test.

Summary of Clinical Testing

Not applicable.

Conclusion

Medline Industries, Inc. concludes that the Medline Sharps Containers are substantially equivalent to the predicate device [Medline Sharps Container (K132767)] as described herein.